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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/184,572	11/02/1998	LISA MCKERRACHER	99999/MARUSY	4396

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EXAMINER	
TURNER, SHARON L	

ART UNIT	PAPER NUMBER
1647	

DATE MAILED: 09/08/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/184,572	MCKERRACHER ET AL.	
	Examiner	Art Unit	
	Sharon L. Turner	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 June 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *25-29 and 35-44* is/are pending in the application.

4a) Of the above claim(s) *25-29* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *35-44* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *6-9-04, 6-4-03*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Response to Amendment

1. The amendment filed 6-9-04 has been entered into the record and has been fully considered.

2. The text of Title 35 of the U.S. Code not reiterated herein can be found in the previous office action.

3. As a result of Applicant's amendment, all rejections not reiterated herein are withdrawn by the Examiner.

4. Claim 34 is canceled. Claims 25-29 and new claims 35-44 are pending.

5. Claims 25-29 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 10.

Priority

6. Receipt of the priority document is acknowledged. However, it is noted that the data presented in the priority document and the specification as filed 11-2-98 differ substantially. In particular the disclosure of the priority document is limited to C3 transferase mediated suppression of the inhibition of axon outgrowth in PC12 cells in vitro, whereas the specification of the application exemplifies C3 transferase mediated suppression of the inhibition of axon outgrowth in crushed optic nerve, an in vivo exemplification. The PC12 in vitro data is not an art accepted model for prediction of a method of stimulating regenerative growth of damaged neuronal axons in a patient with traumatic nervous system damage, see for example Crutcher et al., CRC Crit. Rev. in

Neurobiol., 2(3):297-33, 1986, p. 298, lines 17-18 which teach that the relevance of the data from PC12 cells to normal neuronal growth is not clear. Therefore, the effective filing date awarded instant claims is that of the '572 application filing date, 11-02-1998.

Applicants argue in the response of 6-9-04 that the Crutcher et al reference was published more than ten years before the filing date and that in the interim significant progress in the understanding of neuronal damage and repair was made as opposed to 'only recently being established' as in Crutcher, 1986. Applicants further argue that the IDS submission demonstrates the known inability of damaged neruonal axons to grow in vivo as seen in PC12 cells cultured on myelin with reference to Tomaselli, Rubin and Daniels. Applicants thus assert correlation between in vitro behavior in PC12 cells and in vivo failure of neuronal repair. Applicants further note that the '841 application references at p. 3, lines 11-13 that the antagonist used in the claimed in vivo method has the activity on PC12 cells in vitro taught by the application. Thus, applicants request award of the priority date.

Applicant's arguments filed 6-9-04 have been fully considered but are not persuasive. Applicants claims are directed to "A method of stimulating regenerative growth of damaged neuronal axons in a patient with traumatic nervous system damage..." It is true as noted by Applicants that the art recognizes a relative inability for damaged neuronal axons to grow in vivo. Tomaselli notes the activity of integrins in mediating neurite outgrowth of PC12 cells, Rubin notes inhibition of PC12 cell neurite outgrowth on myelin substrates and Daniels notes the role of PAK1 on neurite outgrowth in PC12 cells. However, neither Tomaselli, Rubin nor Daniels provides a

correlation for the stimulation of neurite outgrowth in neuroblastoma (PC12) cells and the stimulation of regenerative growth in damaged neuronal axons in vivo, in a patient with traumatic nervous system damage. The cell culture experiments are not recognized in the art as sufficient evidence of regenerative effects in vivo. There is no evidence that factors testing positive in the in vitro assay are predictable or correlative to such effects in vivo during traumatic neuronal damage. Furthermore, the in vitro PC12 neurite outgrowth test is not associated with traumatic nervous system damage. No in vivo teachings are noted in Tomaselli, Rubin or Daniels. Applicants referral to p. 3, lines 11-13 of the '841 application notes that "Consistent with the observations in vivo, it was found that dominant negative Rac expressed in PC12 cells disrupts neurite outgrowth in response to NGF (Hutchens et al., 1997)." However, the Hutchens reference has not been made of record. As cited in the priority document, Applicant's are apparently referring to a reference entitled, "Structurally similar Drosophila α-tubulins are functionally distinct in vivo." Yet notably, any relationship between PC12 cell experimentation in vitro and prediction of axonal regeneration in vivo appears to be lacking from the subject line of this reference. Thus, the Hutchens reference, not of record, is ineffective to evidence that the in vitro data of C3 mediated neurite outgrowth in PC12 neuroblastoma cells on myelin is predictive of and enabling for a method of stimulating regenerative growth of damaged neuronal axons in a patient with traumatic nervous system damage as claimed.

In addition, the priority document lacks full disclosure of the specifics of treatment and administration as instantly claimed. In particular, support is not found within the

priority application for the specifics of the claims as directed to administration, "in a nerve" as newly recited in claim 35. Further, the specifics of optic nerve injury, crush injury and regenerative (axon) growth and delivery from gelfoam administration (wrapped around the injured nerve) as recited in claims 37-41 and 44 is not found. Thus, the effective filing date of instant claims is that of the filing date, 11-2-1998.

Rejections as Necessitated by Amendment

Claim Rejections - 35 USC § 112

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claims 35-44 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

New claim 35 recites, "the method comprising delivering directly at a traumatic lesion site in a nerve in a patient, in an amount effective to suppress inhibition of neuronal axon growth." Applicants point to support for such recitations at p. 14, lines 7-8, p. 19, lines 7-8, p. 11, line 1, p. 29, line 22 and original claim 21. However, the specification at such points does not apparently support the particular administration, "in a nerve." Notably the recitation 'in a nerve' is directed to intracellular administration whereas the specification indicates administration around or on a nerve (extracellular

administration) as noted via gel foam wrapped around the nerve. Thus, the recitation constitutes new matter absent evidence of support.

9. Claims 35-44 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The specification describes that C3 ADP-ribosyl transferase stimulates neurite outgrowth in PC12 neuroblastomas and mediates axonal outgrowth in optic nerve crush. However, the claims as written include biologically active fragments of C3 ADP-ribosyl transferase in the absence of any guidance over which fragments are suitable to provide for 'biological activity' or any guidance as to the specific biological activity or function intended to be encompassed by the claim. Further there is no guidance for any assay for assessing whether or not a particular fragment possesses such 'biological activity.' The instant disclosure of a single polypeptide, that of C3 ADP-ribosyl transferase, does not adequately support the scope of the claimed genus, which encompasses a substantial variety of subgenera. A genus claim may be supported by a representative number of species as set forth in *Regents of the University of California v Eli Lilly & Co,* 119F3d 1559, 1569, 43 USPQ2d 1398, 1406 (Fed. Cir. 1997), which states:

"To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention". Lockwood v. American Airlines, Inc., 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (1997); In re Gosteli, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1980) ("[T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is

claimed.") Thus, an applicant complies with the written description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." Lockwood, 107 F.3d 1565, 1572, 41 USPQ2d at 1966.

An adequate written description of a DNA, such as the cDNA of the recombinant plasmids and microorganisms of the '525 patent, "requires a precise definition, such as by structure, formula, chemical name, or physical properties," not a mere wish or plan for obtaining the claimed chemical invention. Fiers v. Revel, 984 F.2d 1164, 1171, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993). Accordingly, "an adequate written description of a DNA requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it; what is required is a description of the DNA itself." Id at 1170, 25 USPQ2d at 1606."

A description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus, or of a recitation of structural features common to the genus, which features constitute a substantial portion of the genus. The instant specification discloses, however, a single isolated polypeptide and no other fragments that are proposed to possess the same 'biological activity.' Thus, the claims lack adequate written description support.

10. Claims 35-44 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for in vitro stimulation of PC12 neurite outgrowth via contact with C. botulinum C3 exoenzyme, and in vivo stimulation of regenerative growth in crushed optic nerve injury via gelfoam administration around the nerve, does not reasonably provide enablement for a method of stimulating regenerative growth of damaged neuronal axons in a patient with traumatic nervous system damage in vivo as

claimed. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The specification is insufficient to enable one skilled in the art to practice the invention as broadly claimed without undue experimentation. The factors relevant to this discussion include the quantity of experimentation necessary, the lack of working examples, the unpredictability of the art, the lack of sufficient guidance in the specification and the breadth of the claims.

The newly amended claims are directed to 'A method of stimulating regenerative growth of damaged neuronal axons in a patient with traumatic nervous system damage, the method comprising delivering directly at a traumatic lesion site in a nerve in a patient in an amount effective to suppress inhibition of neuronal axon growth, a Rho family antagonist selected from the group consisting of (a) a C3 ADP-ribosyl transferase; and (b) biologically active fragments of (a), wherein the antagonist stimulates regenerative growth of damaged neuronal axons across and through the lesion site, and wherein the antagonist has the ability, when scrape loaded into PC12 cells in vitro to produce outgrowth of PC12 cell neurites, the PC12 cells being plated on growth inhibitory substrate selected from the group consisting of myelin and myelin-associated glycoprotein substrate. It is noted that the 2nd wherein clause is deemed to be limiting only as to the antagonists of the claims and not the method steps or requirements of the method. If this interpretation is not correct, applicants should clarifiy the scope as noted in the 112, 2nd paragraph rejection below.

Applicants specification exhibits neurite outgrowth in PC12 neuroblastoma cells in culture, including on myelin substrates. In an in vivo optic nerve crush model, the specification teaches that administration of C3 transferase was effective to allow axons to extend through and beyond the crush site.

Neuronal regeneration is a highly complex process that is unpredictable in the art. For example, Liuzzi, Neurosurgery Clinics of North America, 2(1):31-42, 1991 notes such factors as survival, the severity of the lesion, the type of nerve involved in injury, the extracellular environment, the presence or absence of growth factors, and the presence or absence of inhibitory factors to the growth and regenerative capacity in nerve injury. Further, Jackowski et al., British Journal of Neurosurgery 9 :303-317, 1995, notes significant barriers to effective regeneration within the central nervous system CNS and in vivo. As noted in Davies (1997) Nature 390, 680-683, see in particular Abstract, "It is widely accepted that the adult mammalian central nervous system (CNS) is unable to regenerate axons. In addition to physical or molecular barriers presented by glial scarring at the lesion site, it has been suggested that the normal myelinated CNS environment contains potent growth inhibitors or lacks growth-promoting molecules."

However, Applicants claims are directed to any type of damaged neuronal axons in a patient with trauma. Yet in contrast to Applicants in vivo model system, the art recognizes severe neuronal injuries such as in complete transection of the nerve or in nerve crush where neuronal survival and scar formation is a significant limiting factor. These injuries are associated with neuronal cell death and extensive scarring that is

actively inhibitory to regeneration. Such injuries may involve any neuronal fiber tract of the central or peripheral nervous system, see in particular Liuzzi, Davies and Jackowski.

Further with regard to the specifics of administration as directed to an "amount effective to suppress inhibition of neuronal axon growth", the particulars of administration and the means for assessing this required effect is not noted by the claim or recognized in the art. The amount would presumably differ depending on the type of injury. Not only are the claims required to suppress inhibition of neuronal axon growth, the claims must meet the preamble as to "stimulating regenerative growth of damaged neuronal axons in a patient with traumatic nervous system damage " and the growth must be, "across and through the lesion site," (if the 1st wherein clause is limiting to the requirements of the regenerative growth of the claim).

To practice such a method would require knowledge of the route, duration and quantity of administration of C3 transferase or fragment thereof to the patient. While a particular quantity is noted for the optic nerve crush model as exemplified, the specification fails to teach a means for predictably assessing such particulars for the generic scope of traumatic injuries as encompassed by the claims and which would include complete transection of both PNS and CNS tissue in vivo. Further, the instant specification fails to disclose how these parameters are to be determined, how a similar method was practiced in the art with a different agent or in a different in vivo trauma system. The specification lacks specific guidance as to the effects and suitable models for spinal cord injury, lesion or surgical lesion as in claim 42. In the absence of these specifics a practitioner would have to resort to a substantial amount of undue

experimentation involving the variation in the amount and duration of administration to a host of differing neuronal trauma models, in order to determine appropriate treatments. It is further noted that the only inhibitor disclosed as having such activity in the specification is C. botulinum C3 exoenzyme, whereas the claims encompass administration of fragments. While the specification further notes that the antagonists are to stimulate regenerative growth and produce neurite outgrowth on PC12 cells in the presence of myelin substrates, the specification fails to teach that such assays are suitably predictive of stimulating in vivo regenerative growth within the scope of 'traumatic injuries' which would be inclusive of transection injuries in the CNS and PNS in vivo.

Moreover, the claims are directed to "biologically active fragments of C3 transferase" in the absence of any guidance as to what biological activity is encompassed. No fragments are noted to provide the desired biological activity and there is no means noted within the claim for assessing it. The specification does not enable the broad scope of the claims that encompass a multitude of analogs or equivalents because the specification does not teach which residues can or should be modified such that requisite functionality is maintained, note utility rejection above. The specification provides essentially no guidance as to which of the essentially infinite possible choices is likely to be successful in any particular use and the skilled artisan would not expect functional conservation amongst homologous sequences. Thus, applicants have not provided sufficient guidance to enable one skilled in the art to make and use the claimed derivatives in a manner reasonably correlated with the scope of the

claims.

The scope of the claims must bear a reasonable correlation with the scope of enablement (In re Fisher, 166 USPQ 19 24 (CCPA 1970)). Without such guidance, the changes which can be made and still maintain activity/utility is unpredictable and the experimentation left to those skilled in the art is unnecessarily, and improperly, extensive and undue. See Ex parte Forman, 230 USPQ 546 (Bd. Pat. App. & Int. 1986). Thus, the skilled artisan cannot readily make and use the claimed sequences without further undue experimentation.

The instant situation is directly analogous to that which was addressed in *In re Colianni*, 195 U.S.P.Q. 150,(CCPA 1977), which held that a "[d]isclosure that calls for application of "sufficient" ultrasonic energy to practice claimed method of fusing bones but does not disclose what "sufficient" dosage of ultrasonic energy might be or how those skilled in the art might select appropriate intensity, frequency, and duration, and contains no specific examples or embodiment by way of illustration of how claimed method is to be practiced does not meet requirements of 35 U.S.C. 112 first paragraph".

A patent is granted for a completed invention, not the general suggestion of an idea and how that idea might be developed into the claimed invention. In the decision of *Genentec, Inc, v. Novo Nordisk*, 42 USPQ 2d 100,(CAFC 1997), the court held that:

> "[p]atent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable" and that "[t]ossing out the mere germ of an idea does not constitute enabling disclosure". The court further stated that "when there is no disclosure of any specific starting material or of any of the conditions under which a process is to be carried out, undue experimentation is required; there is a failure to meet the

enablement requirements that cannot be rectified by asserting that all the disclosure related to the process is within the skill of the art", "[i]t is the specification, not the knowledge of one skilled in the art, that must supply the novel aspects of an invention in order to constitute adequate enablement".

The instant specification is not enabling because one cannot following the guidance presented therein, practice the claimed method without first making a substantial inventive contribution. The artisan would be required to determine how to effect regenerative growth in a host of neuronal diseases and injuries. The artisan must choose the inhibitor, the particular patient, the amount of the selected compound, a suitable delivery method, dosage regime and duration for the required response. These selections would only after further undue experimentation arrive at the invention now claimed because the claims fail to delineate predictable methods for assessing such as claimed.

The specification is required to enable the artisan to practice the invention without further undue experimentation. The scope of the claims must bear a reasonable correlation with the scope of enablement (In re Fisher, 166 USPQ 19 24 (CCPA 1970)). Without such guidance, the method is unpredictable and the experimentation left to those skilled in the art is unnecessarily, and improperly, extensive and undue. See Ex parte Forman, 230 USPQ 546 (Bd. Pat. App. & Int. 1986).

11. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

12. Claims 35-44 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

It is noted that the wherein limitations after element (b) are indefinite with respect to whether they are intended to further limit the antagonist or recite a requirement of the method treatment. For example, the recitation "wherein the antagonist stimulates regenerative growth of damaged neuronal axons across and through *a* lesion site" would appear to be a limitation on the antagonist as the wherein clause refers to the antagonist. However, the limitation also appears to be directed to the growth as the recitation refers to 'the lesion site', yet the wherein clause does not refer to 'the regenerative growth' of the claimed method but to the 'antagonist'. It is suggested that if the limitation is intended to be a requirement of the method that clear antecedent basis to "the regenerative growth of the damaged neuronal axons across and through the traumatic lesion site," be recited, whereas if the limitation is to be reflective of the scope of antagonists chosen, (as in the 2nd wherein clause) that the limitation clearly specify a selective assay to determine the suitable antagonists and that the article "the" prior to "lesion" be removed, i.e., wherein the selected antagonist is capable of stimulating regenerative growth of damaged neuronal axons across and through a lesion site." The second wherein clause is also suggested to recite, "wherein the selected antagonist".

Further, as to the recitation of "biologically active fragments", the artisan does not recognize the biological activity to which the claims are referring and no specific biological activity is recited within the claims. Hence the artisan has no guidance whereby to assess the suitable fragments encompassed. It appears that applicants may wish the 'biological activity' to be assessed via the 2nd wherein clause. However, the claims do not recite such via reference to 'the biological activity'.

Claims 40-41 recite the limitation "regenerative axon growth", whereas claim 35 recites "regenerative growth." It is suggested that the terminology be consistent between the two recitations such that clear antecedent basis is provided for all terms.

Claim 44 recites "the damaged nerve at the crush site", whereas neither claims 38 nor 35 recite this limitation, but instead refer to "the lesion site" and "a site of nerve crush injury." Thus, there is insufficient clear antecedent basis for this limitation in the claim. The terminology should be consistent between the two recitations such that clear antecedent basis is provided for all terms.

Status of Claims

13. No claims are allowed.

14. The Liao and Johnson prior art rejections of record are withdrawn in view of Applicant's claim amendments. The prior art does not teach or fairly suggest administration "in a nerve" as claimed. However, it is noted that this recitation is deemed to be unsupported (new matter) as set forth above. Amendment that removes this limitation may necessitate reinstatement of art rejections over these references.

Conclusion

15. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within

TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

16. Any inquiry of a general nature or relating to the status of this general application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Papers relating to this application may be submitted to Technology Center 1600, Group 1640 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). Should applicant wish to FAX a response, the current FAX number for Group 1600 is (703) 872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharon L. Turner, Ph.D. whose telephone number is (571) 272-0894. The examiner can normally be reached on Monday-Friday from 8:00 AM to 4:30 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached at (571) 272-0961.

Sharon L. Turner, Ph.D.
September 7, 2004

SHARON L. TURNER, PH.D.
PATENT EXAMINER
9-7-04